UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,653	07/18/2003	Brian Robert Walker	43-2003	3827

20999 7590 09/13/2006

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,653	WALKER ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/18/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a method of using a modulator of glucocorticoid metabolism in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response, classified in class 435, subclass 69.2+.

II. Claims 4-7, drawn to an engineered macrophage having increased endogenous biosynthesis of active glucocorticoid, classified in class 424, subclass 93.21.

III. Claims 8-17, drawn to a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response in a mammal, classified in class 514, subclass 179.

IV. Claims 18-21, drawn to a pharmaceutical composition comprising a glucocorticoid in inactive form, classified in class 514, subclass 179.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method of using a modulator of glucocorticoid

metabolism in the manufacture of a composition for the potentiation of an inflammatory response and an engineered macrophage.

Because these inventions are distinct and the search required for Groups I is not required for Group II, restriction for examination purposes as indicated is proper. More specifically, the search for a method of using a modulator of glucocorticoid metabolism in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response of Group I will not lead to art on an engineered macrophage. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group I and Group II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method of using a modulator of glucocorticoid metabolism in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response and a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response.

Because these inventions are distinct and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. More

specifically, the search for a method of using a modulator of glucocorticoid metabolism in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response of Group I may not necessarily lead to art on a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a successful resolution of the inflammatory response. The searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group I and Group III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method of using a modulator of glucocorticoid metabolism in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response and a pharmaceutical composition comprising a glucocorticoid in inactive form.

Because these inventions are distinct and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. More specifically, the search for a method of using a modulator of glucocorticoid metabolism in the manufacture of a composition for the potentiation of a successful resolution of an inflammatory response of Group I may not necessarily lead to art on a pharmaceutical composition comprising a glucocorticoid in inactive form. The searches in non-patent

literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group I and Group IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to an engineered macrophage and a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a successful resolution of the inflammatory response in a mammal.

Because these inventions are distinct and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper. More specifically, the search for an engineered macrophage will not lead to art on a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a successful resolution of the inflammatory response in a mammal. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group II and Group III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

6. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs,

modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to an engineered macrophage and a pharmaceutical composition comprising a glucocorticoid in inactive form.

Because these inventions are distinct and the search required for Group II is not required for Group IV, restriction for examination purposes as indicated is proper. More specifically, the search for an engineered macrophage will not lead to art on a pharmaceutical composition comprising a glucocorticoid in inactive form. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group II and Group IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

7. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a successful resolution of the inflammatory response in a mammal and a pharmaceutical composition comprising a glucocorticoid in inactive form.

Because these inventions are distinct and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper. More specifically, the search for an a method of using a glucocorticoid or 11-dehydrocorticosteroid in the manufacture of a composition for the potentiation of a

successful resolution of the inflammatory response in a mammal will not lead to art on a pharmaceutical composition comprising a glucocorticoid in inactive form. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group III and Group IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

8. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

9. It will be a burden on the examiner to search all the invention as claimed for the reasons cited above. Applicant is requested to elect a single disclosed species from the elected group for search purposes.

10. A telephone call was made to Mr. Thomas Kowalski on 08/29/06 to request an oral election to the above restriction requirement, but did not result in an election being made. Mr. Kowalski will contact the inventors and get back to the examiner. Mr. Kowalski's cooperation is greatly appreciated.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nathan W. Schlientz, Ph.D.
Patent Examiner
Technology Center 1600

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sabiha Qazi
Primary Patent Examiner
Technology Center 1600